# Evaluation of UriSed 3 automated urine microscopy analyser

Urinalysis may provide evidence of significant renal disease in asymptomatic patients. The microscopic urinalysis is vital to making diagnoses in many asymptomatic cases, including urinary tract infection, urinary tract tumors, occult glomerulonephritis, and interstitial nephritis.

Presence or absence of different particles in urine sediment is crucial for clinical decision making. Urine sediment cells or particles provide important information for the diagnosis of renal or urinary diseases [1]. The patented UriSed Technology was developed to reduce the shortcomings of manual microscopy through automation. [2]. The UriSed analysers provide a reliable and reproducible solution since 2007 [3]. The new generation instrument based on the improved UriSed Technology, UriSed 3 was introduced in the market in 2015. UriSed 3 is an automated urine microscopy analyser with a revolutionary particle visualization utilizing both bright-field and phase-contrast microscopy. In the present study, we evaluated the analytical performance of UriSed 3 Automated Urine Microscopy Analyser (Manufactured by 77 Elektronika Kft., Budapest) and compared the results to those from manual microscopy using standardized KOVA counting chambers.

UriSed 3 provides quantitative Red Blood Cell (RBC) and White Blood Cell (WBC) results, and semi-quantitative results for all other particle types: WBC Clumps (WBCc), Squamous Epithelial Cells (EPI), Non-squamous Epithelial Cells (renal tubular and urothelium cells) (NEC), Crystals (CRY): Calcium oxalate dihydrate (CaOxd), Calcium oxalate monohydrate (CaOxm), Uric acid (URI), and Triple-phosphate crystals (TRI), Hyaline casts (HYA), Pathological casts (PAT), Bacteria (cocci-like and rod-like) (BACc, BACr), Yeasts (YEA), Spermatozoa (SPRM) and Mucus (MUC) [4].

## Phase-contrast microscopy by UriSed 3

Phase-contrast microscopy is an optical microscopy technique that converts phase shifts in light passing through a transparent specimen to brightness changes in the image. Phase shifts themselves are invisible, but become visible when shown as brightness variations. In particular, for urinary sediment examination, phase-contrast supplies an optimal identification of particles with a low refractive index (e.g., hyaline casts and RBC devoid of their hemoglobin content, the so-called "ghost RBC") and of cellular morphological details) [9, 10]. Therefore the use of phase-contrast microscopy is encouraged also by international guidelines on urinalysis [5, 6].

The measurement technique of the UriSed 3 instrument is a combination of a bright-field microscope and a phase-contrast microscope in one optical system. Preparation of the UriSed 3 analyser for measurement takes only a few minutes. It needs distilled water for washing its pipette, and patented disposable plastic cuvettes for sample investigation. The instrument throughput is up to 120 samples per hour. The whole measurement process is completely automatic: 200 µl of urine sample is dispensed into the cuvette, then spinning the cuvette for a few seconds gently deposits formed elements into a monolayer at the bottom of the cuvette. The built-in digital camera takes and saves both a bright-field and a phase-contrast microscopic image from the same view-field at 15 different positions of the sediment layer. Information from both whole view-field images are evaluated by a neural network based image processing software.

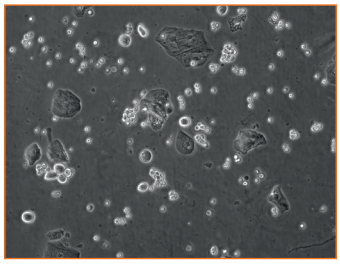

UriSed 3.

## Material and methods

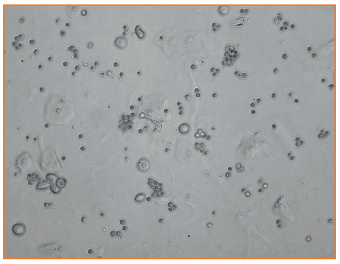
Analysis of 311 samples was performed to evaluate UriSed 3 analytical performance compared to the manual microscopy urine examination method. Both measurements were carried out with the same anonymous urine samples. Fresh, native urine samples were used, that were typically held for no more than 4 hours before being analysed, as recommended in the relevant guidelines [5,6] to prevent change in the morphology of the particles. Samples were mixed until homogeneous and then split and run on each measuring procedure as close to the same time as possible. The standardized microscopic urinalysis of native samples (Level 3) was followed by using a KOVA counting chamber. The particle concentration for all particle types was evenly distributed in the evaluated urine samples. Carry-over, precision, diagnostic tests such as sensitivity, specificity, diagnostic accuracy, concordance and one category concordance were investigated according to well-established protocols [7].

## Results

No carry-over was detected in any of the samples. UriSed 3 has better precision than microscopy at all of the tested RBC and WBC concentrations. The majority of all coefficients of variation obtained for within series imprecision (CV) using UriSed 3 was 7-16% versus 5,5-67% in case of manual microscopy [8]. Good correlation can be found between UriSed 3 and manual counting chamber for formed elements. The Pearson correlation of quantitative parameters are 0.91 (RBC), 0.93



Phase-contrast image taken by UriSed 3.



Bright field image taken by UriSed 3.

(WBC). The clinical evaluation of UriSed 3 was based on McNemar test and concordance study. The results are shown in the table above.

## Conclusion

UriSed 3 instruments utilize phase-contrast and bright-field microscopy to combine original and innovative technologies whose aim is the progressive improvement of automated urinary sediment examination and the progressive approach to the gold standard manual microscopy method. The automated measurement process of UriSed 3 is reproducible and operator-independent. Those sediment particles that are mostly transparent become visible with phase-contrast microscopy by UriSed 3, which is a spectacular advantage and leads to specific improvement in recognition at several particle types.

## References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| Particle | Sensitivity | Specificity | Accuracy | Concordance | ±1 Category Concordance |
|---|---|---|---|---|---|
| RBC | 87% | 87% | 87% | 71% | 96% |
| WBC | 89% | 90% | 89% | 98% | 90% |
| EPI | 81% | 91% | 89% | 83% | 98% |
| NEC | 81% | 79% | 79% | 69% | 97% |
| HYA | 77% | 86% | 84% | 78% | 95% |
| PAT | 69% | 97% | 84% | 80% | 93% |
| CRY | 83% | 99% | 97% | 94% | 96% |
| YEA | 68% | 99% | 91% | 89% | 97% |
| BAC | 93% | 88% | 89% | 85% | 99% |
| MUC | 77% | 84% | 83% | 77% | 95% |

Clinical evaluation results of UriSed 3 compared to manual microscopy.